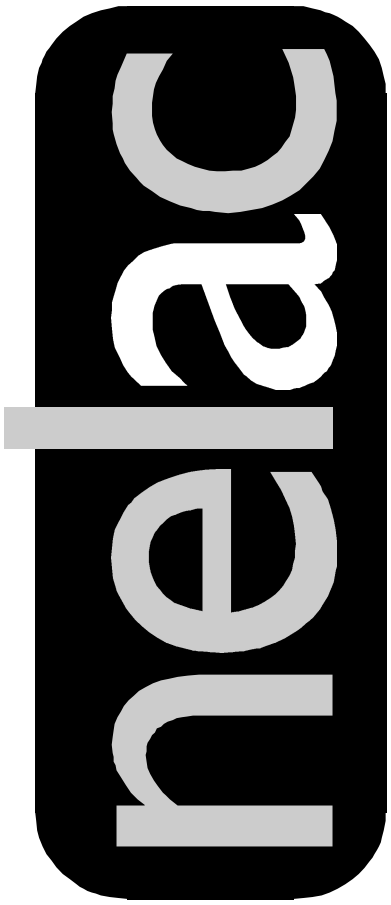
National Environmental Laboratory **Accreditation** Conference



PROFICIENCY TESTING

PROPOSED

April 29, 1999

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PROFICIENCY TESTING

NOTE: ***Additions (double-underlined) and ~~deletions~~ (struck through) to the approved standards being proposed for vote at the Fifth Annual Meeting are marked as in this note.***

2.0 PROFICIENCY TESTING PROGRAM: INTERIM STANDARDS

For the period beginning with adoption of these standards by the National Environmental Laboratory Accreditation Conference (NELAC) and ending July 31, 1999, all National Environmental Laboratory Accreditation Program (NELAP)-approved ~~p~~Primary ~~a~~Accrediting ~~a~~Authorities shall accept data only from proficiency testing programs that meet the requirements of current U.S. Environmental Protection Agency (USEPA) and state regulations~~.~~. Following implementation of the National Institute of Standards and Technology (NIST) National Voluntary Laboratory Accreditation Program (NVLAP) for Providers of Proficiency Testing, and before a Proficiency Test Provider distributes PT samples to laboratories for the purpose of the laboratories obtaining or maintaining NELAP accreditation, the provider shall first obtain NVLAP accreditation for all compounds/matrices for which NIST accreditation is available, and for which the provider intends to provide NELAC PT samples. The intent of these interim standards is to ensure that ~~p~~Primary ~~a~~Accrediting ~~a~~Authorities accept for the purposes of NELAP accreditation all PT samples which are distributed by PT Providers which are NIST/NVLAP accredited for those compounds / matrices, and to continue the status quo for all other programs and compounds for which NIST NVLAP accreditation is not currently available.~~–~~

2.1 INTRODUCTION, SCOPE, AND APPLICABILITY

This chapter and the associated appendices define the major participating organizations and components of the NELAC Proficiency Testing (PT) Program. In addition to complying with the requirements of this ~~C~~chapter, any person, private party or government entity seeking to participate as a NELAP-approved PT Provider ~~in the NELAC program~~ shall also comply with the requirements of the applicable Appendices A (PT Provider Approval Criteria), B (PT Sample Design and Acceptance Guidelines), C (Proficiency Testing Acceptance Criteria ~~and Proficiency Testing Pass/Fail Criteria~~) ~~and~~, D (Proficiency Testing Oversight ~~Body~~Body/Proficiency Test Provider Accreditor), E (Microbiology), and F (Environmental Toxicology). The criteria set forth in these standards shall be used by laboratories and PT Providers for the purposes of obtaining or maintaining NELAP accreditation or NELAP approval.

In addition to complying with the requirements of this ~~C~~chapter and ~~A~~appendices, any entity seeking to participate as a NELAP-approved PT Provider ~~in the NELAP program~~ shall also comply with all applicable requirements of "National Standards for Water Proficiency Testing Studies, Criteria Document", U.S. Environmental Protection Agency or other NELAC documents that define analytes, analyte numbers, concentrations, and acceptance criteria as required in Section C.~~-~~1.1.2.

Proficiency ~~T~~testing (PT) is defined for the purpose of this ~~C~~chapter as a means of evaluating a laboratory's performance under controlled conditions relative to a given set of criteria through analysis of unknown samples provided by an external source. PT is not the sole criterion for determining accreditation status. Additional essential elements of the overall NELA~~C~~P accreditation process, including the~~–~~ on-site assessment, are discussed in other chapters of the NELAC standards. The PT program is intended to cover all types of federal and state environmental analyses. However, the body of the PT standard applies primarily to chemistry. ~~*Appendices (yet to be developed) shall describe necessary variations as applied to radiochemistry, environmental toxicology, and microbiology.*~~

The major components of the NELAC PT ~~P~~program include:

a) multiple PT Providers who shall meet stringent criteria to become ~~A~~approved by a Proficiency Testing Oversight Body (PTOB)/Proficiency Test Provider Accreditor (PTPA), as described in Section 2.3 and Appendix A;

b) specific requirements for the design of PT samples and studies, to ensure that all samples provide a consistent, fair and known challenge to laboratories seeking accreditation from a NELAP-approved ~~a~~Accrediting ~~a~~Authority, as described in Section 2.3 and Appendix B;

c) specifically defined ~~pass/fail~~acceptable/not acceptable criteria for evaluating PT sample results, as described in Section 2.3 and Appendix C;

d) initial approval and ongoing oversight of PT Providers by a Proficiency Testing Oversight Body (PTOB)/Proficiency Test Provider Accreditor (PTPA), Section 2.3 and Appendix D;

e) specific requirements for laboratories participating in PTOB~~-~~/PTPA-approved PT ~~P~~programs, as described in Sections 2.4, 2.5, and 2.7; and

f) oversight of all PT ~~P~~program activities by the PTOB(s)/PTPA(s), as described in Section 2.2.~~1~~2.

2.1.1 Purpose

The PT program incorporates several practical purposes, which include:

a) the production and supply of test samples that are procedure-sensitive; that is, the samples challenge the critical components of each analytical procedure, ranging from initial sample preparation to final data analysis;

b) the production and supply of test samples that are as similar to real-world samples as is reasonably possible. It is further expected that the PT samples shall be representative of materials analyzed for environmental regulatory programs, agencies, and communities;

c) a program which is affordable by all participants;

d) the yielding of PT data that are technically defensible on the basis of the type and quality of the samples provided;

e) the preparation of samples such that the identification and quantitation of analytes in the samples poses equivalent difficulty and challenge regardless of the manner in which the samples are designed and manufactured by the PT Providers, i.e. samples prepared for analysis by a ~~D~~drinking ~~W~~water or ~~W~~wastewater method would pose equal challenge whether prepared as whole volume or~~-~~ as a concentrate in ampules.

2.1.2 Goals

The PT program incorporates several practical goals, which include:

a) the generation of data at a quality level required by environmental and regulatory programs;

b) the generation of data that are, at a minimum, comparable in quality to that of currently certified and/or accredited laboratories; and

c) the improvement of the overall performance of laboratories over time.

2.1.3 PT Fields of Testing

The PT program is organized by PT fields of testing. ~~Laboratories may choose to participate in one or more PT fields of testing.~~ The following elements collectively define PT fields of testing:

a) ~~R~~regulatory or environmental program, as listed in Chapter 1,

b) ~~M~~matrix type (e.g. gas, aqueous liquid, nonaqueous liquid, solid), and

c) ~~A~~analyte

2.2 MAJOR PT GROUPS AND THEIR RESPONSIBILITIES

The PT program structure incorporates five major groups with separate and distinct roles and responsibilities. The groups are NELAC, the Proficiency Testing Oversight Body (PTOB)/Proficiency Test Provider Accreditor (PTPA), the PT Providers, the testing laboratories, and the ~~p~~Primary Accrediting Authorities (AA). The lines of interaction among these groups are shown in Figure 2-1.

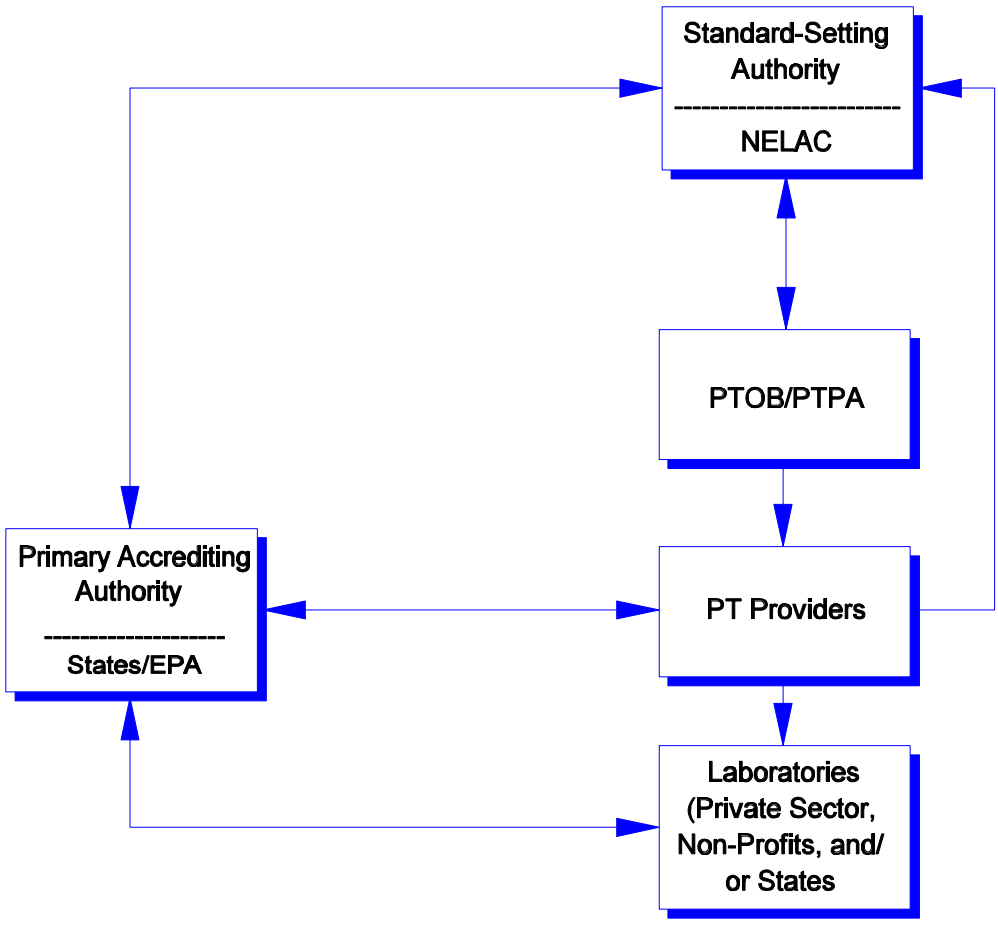

Figure 2-1. NELAP Proficiency Testing

2.2.1 Proficiency Testing Study Providers

The ~~p~~PT Providers shall produce and distribute PT samples, evaluate study results against published performance criteria, and report the results to the laboratories, the respective ~~p~~Primary Accrediting Authorities, the appropriate PTOB/PTPA, and NELAP. The PT Provider shall meet the requirements of Appendix A, manufacture samples that meet the requirements of Appendix B, and score sample results in accordance with the requirements of Appendix C.

2.2.2 Proficiency Testing Oversight Body (PTOB)/Proficiency Test Provider Accreditor (PTPA)

The Proficiency Testing Oversight Body (PTOB)/Proficiency Test Provider Accreditor (PTPA) establishes and implements a program to accredit PT ~~study suppliers~~Providers and to monitor accredited ~~suppliers~~providers to ensure that their studies and practices meet all applicable standards. The PTOB/PTPA shall meet the requirements of Appendix D. Organizations meeting the requirements of this ~~S~~standard and its appendices, as determined by the NELAC Standing Committee on Proficiency Testing, may be nominated by the ~~C~~committee to NELAP to be designated as a PTOB/PTPA. NELAP may approve or disapprove the designation of an organization as a PTOB/PTPA. The ~~C~~committee may also recommend to NELAP that a PTOB/PTPA's designation be withdrawn for failing to meet the criteria in this standard and appendices.

2.2.3 Laboratories

Laboratories that seek to ~~become accredited~~ obtain or maintain accreditation shall perform analyses of PT samples for each PT field of testing as ~~required by this chapter~~defined in Section 2.1.3. PT samples shall be obtained from NELAP designated ~~PTPA- approved~~PTOB/PTPA-approved PT Providers. The laboratory shall obtain PT samples from any so approved PT Provider. The results of the analyses shall be submitted to the PT Provider for scoring. ~~Accrediting Authorities shall accept for the purposes of initial and continuing accreditation, PT results from any NELAP approved provider that meets the requirements of this standard.~~

2.2.4 Accrediting Authorities (AA)

The ~~p~~Primary ~~a~~Accrediting ~~a~~Authorities shall make all decisions regarding a laboratory's accreditation status. They are responsible for taking action to make these determinations including ensuring that laboratories seeking or holding their accreditations have participated in the PT program. Accrediting authorities shall accept for the purposes of initial and continuing accreditation, PT results from any NELAP-approved PT Provider that meets the requirements of this standard.

2.3 REQUIREMENTS FOR PT PROVIDERS

This section and associated Appendix A describe the criteria that all PT ~~p~~Providers shall meet in order to be approved by the PTOB/PTPA as PT Providers. A PTOB/PTPA shall grant approval to PT ~~p~~Providers on a field-of-testing basis, as described in Section 2.1.3.

2.3.1 On-Site Inspection of PT Providers

A PTOB/PTPA shall conduct an on-site inspection of any organization seeking to participate as a NELAP-approved PT Provider ~~in the NELAC Program~~, as described in Appendix D. The PTOB/PTPA shall determine whether the ~~P~~provider meets the applicable requirements described in this ~~C~~chapter and Appendices A, B, and C. Approval of a PT Provider shall be the responsibility

of a PTOB/PTPA. A PTOB/PTPA shall conduct ongoing oversight of the PT Providers as necessary to ensure conformance with all applicable standards.

2.3.2 Sample Requirements and Design

This ~~S~~section and associated Appendix B describe PT sample design and acceptance criteria. The matrices of all PT samples shall, to the extent possible, resemble the matrices for which the laboratory seeks to obtain or maintain accreditation. Samples may not be reused in any subsequent NELAC PT study.

2.3.2.1 Sample Analytes

The PT Provider shall prepare each sample lot such that the prepared concentration of each analyte in each lot is unique. The required group of analytes covering each PT field of testing shall be determined by the NELAC Standing Committee on Proficiency Testing and shall be evaluated and updated, as necessary. ~~Within each study, a certain minimum number of analytes shall be present. The group of analytes included shall change over time so that all analytes are included at least once every three years over a series of sequential studies.~~

2.3.2.2 PT Provider Sample Testing

The PT Provider shall design, manufacture, and test the samples for homogeneity, stability, and verification of prepared values as required by Appendix B. This testing shall verify that the quality of all samples is acceptable for use in each PT field of testing ~~PT study~~.

2.3.3 PT Study Data Analysis

This ~~S~~section and associated Appendix C describe the criteria to be used by PT Providers when scoring and evaluating NELAC PT sample results.

2.3.3.1 Data Acceptance Criteria

PT Providers shall use the data acceptance criteria described in Appendix C to evaluate laboratories' PT data to ensure a laboratory's performance shall be judged fairly and consistently.

2.3.4 Generation of Study Reports

Each PT Provider shall evaluate the data and issue a report within 21 calendar days of the close of each study.

2.3.5 Provider Conflict of Interest

Each PT Provider shall certify that it is free of any organizational conflict of interest. A PT ~~sample producer~~Provider shall never split a sample lot and offer these samples for sale as known-value check samples before the unknown samples are used in a PT study. In addition, each ~~p~~PT Provider shall follow procedures and have systems in place that maintain confidentiality and security of all prepared values through the closing date of each study. All records shall be retained for a period of five years ~~or as required by the appropriate regulatory program~~.

2.3.6 Disapproval of PT ~~Study~~ Providers

A PT Provider's approval may be subjected to revocation per the procedures outlined in Appendix A, Section A.9.2~~-~~.

2.3.7 PTOB/PTPA Listing of PT Providers

PTOBs/PTPAs shall maintain a list of ~~A~~approved PT Providers. PTOBs/PTPAs shall evaluate, update, and publish this list ~~at intervals not to exceed six months. On this same interval, PTOBs/PTPAs shall also publish the list of PT fields of testing necessary to satisfy the PT requirements as determined in Section 2.3.2.1~~as specified in Appendix D.

2.4 LABORATORY ENROLLMENT IN PROFICIENCY TESTING PROGRAM(S)

2.4.1 Required Level of Participation

To be accredited initially and to maintain accreditation, ~~each~~a laboratory shall participate in ~~PT studies provided by a PTPA-approved~~two single-blind, single-concentration PT studies, where available, per year for each PT field of testing for which it seeks or wants to maintain accreditation. Laboratories must obtain PT samples from a PTOB/PTPA-approved PT Provider. ~~Laboratories must participate in PT studies for each field of testing, as described in Chapter 1.~~ Each laboratory shall participate in at least two PT studies for each PT field of testing per year unless a different frequency for a given program is defined in the ~~A~~appendices. ~~The PT Provider shall design studies that require the analysis of one test sample for each field of testing.~~ Section 2.5 describes the time period in which a laboratory ~~must~~shall analyze the PT samples and report the results. Data and laboratory evaluation criteria are discussed in Sections 2.6 and 2.7 of this ~~C~~chapter.

2.4.2 Requesting Accreditation

At the time each laboratory applies for accreditation, it shall notify the ~~p~~Primary ~~a~~Accrediting ~~a~~Authority which field(s) of testing it chooses to become accredited for and shall participate in the appropriate PT studies. For all fields of testing, including those for which PT samples are not available, the laboratory shall ensure the reliability of its testing procedures by maintaining a total quality management system that meets all applicable requirements of Chapter 5 of the NELAC standards.

2.4.3 Reporting Results

~~Laboratories seeking accreditation may select any provider from the list of PTPA-approved PT study providers. The laboratories shall bear the cost of any PT study subscription.~~ Each laboratory shall authorize the PT ~~study p~~Provider to release all accreditation and remediation results and ~~pass/fail~~acceptable/not acceptable status directly to the ~~appropriate a~~Primary Accrediting ~~a~~Authority, NELAP and the PTOB/PTPA, in addition to the laboratory.

2.5 REQUIREMENTS FOR LABORATORY TESTING OF PT STUDY SAMPLES

~~A laboratory must participate in two single-blind, single-concentration PT studies, where available, provided by a PTPA-approved PT provider per year for each field of testing for which it seeks or wants to maintain accreditation.~~ The samples shall be analyzed and the results returned to the PT ~~study p~~Provider no later than 45 calendar days from the scheduled study shipment date. The laboratory's management and all analysts shall ensure that all PT samples are handled (i.e., managed, analyzed, and reported) in the same manner as real environmental samples utilizing the same staff, methods as used for routine analysis of that analyte, procedures, equipment, facilities, and frequency of analysis.

2.5.1 Restrictions on Exchanging Information

Laboratories shall comply with the following restrictions on the transfer of PT samples and communication of PT sample results prior to the time the results of the study are released:

a) A laboratory shall not send any PT sample, or a portion of a PT sample, to another laboratory for any analysis for which it seeks accreditation, or is accredited;

b) A laboratory shall not knowingly receive any PT sample or portion of a PT sample from another laboratory for any analysis for which the sending laboratory seeks accreditation, or is accredited;

c) Laboratory management or staff shall not communicate with any individual at another laboratory (including intracompany communication) concerning the PT sample; and

d) Laboratory management or staff shall not attempt to obtain the prepared value of any PT sample from their PT Provider.

2.5.2 Maintenance of Records

The laboratory shall maintain copies of all written, printed, and electronic records, including but not limited to bench sheets, instrument strip charts or printouts, data calculations, and data reports, resulting from the analysis of any PT sample for five years or for as long as is required by the applicable regulatory program, whichever is greater. These records shall include a copy of the PT study report forms used by the laboratory to record PT results. All of these laboratory records shall be made available to the assessors of the ~~p~~Primary ~~a~~Accrediting ~~a~~Authority during on-site audits of the laboratory.

2.6 EVALUATION OF PROFICIENCY TESTING RESULTS

PT ~~study p~~Providers shall evaluate results from all PT studies using NELAC-mandated acceptance criteria ~~-~~described in Appendix C.~~-~~ The NELAC Standing Committee on Proficiency Testing shall provide, ~~-~~and update as necessary, the data acceptance criteria that all PT ~~study p~~Providers shall use for all PT~~-~~ studies. Each result shall be scored on an acceptable/not acceptable basis. The PT ~~study p~~Provider shall provide the participant laboratories and the ~~p~~Primary ~~-a~~Accrediting ~~a~~Authority a report showing at ~~least~~a minimum the laboratory's reported value, the prepared value, the acceptance range, ~~and~~ the acceptable/not acceptable status, and the method for each analyte reported by the laboratory~~-~~. The~~e~~is report shall be sent no later than 21 calender days from the study closing date. Upon request by either the Primary Accrediting Authorities or laboratories, the PT Provider shall make available a report listing the total number of participating laboratories and the number of laboratories scoring not acceptable for each analyte. The ~~p~~PT Providers shall not disclose specific laboratory results or evaluations to any other parties not described in this section.

2.7 PT CRITERIA FOR LABORATORY ACCREDITATION

2.7.1 Result Categories

The criteria described in this section apply individually to each PT field of testing, as defined by the laboratory seeking to obtain or maintain accreditation in its accreditation request. These criteria apply only to the PT portion of the overall accreditation standard, and the ~~p~~Primary ~~a~~Accrediting ~~a~~Authority ~~shallconsider~~shall consider PT results along with the other elements of the NELAC standards when determining a laboratory's accreditation status. The ~~p~~Primary ~~a~~Accrediting ~~a~~Authority ultimately makes all decisions regarding the accreditation status of the laboratory. There are two PT result categories: "acceptable" and "not acceptable."

2.7.2 Initial and Continuing Accreditation

A laboratory ~~seeking~~ to obtain or maintain accreditation shall successfully complete two PT studies for each requested PT field of testing within the most recent three rounds attempted. Successful performance is described in Appendix C. Once a laboratory has been granted accreditation status, it ~~must~~shall continue to complete PT studies for each PT field of testing and maintain a history of at least two ~~acceptable~~ PT studies for each PT field of testing out of the most recent three. For initial accreditation or ~~remedial~~supplemental testing, the PT studies ~~must~~shall be at least 30 calendar days apart. ~~For~~ For continuing accreditation, completion dates of successive proficiency rounds for a given PT field of ~~study must~~testing shall be approximately six months apart. Failure to meet the semiannual schedule is regarded as a failed study ~~after seven months~~.

2.7.3 Supplemental Studies

A laboratory may elect to ~~participate~~ participate in PT studies more frequently than required by the semiannual schedule ~~as set by the primary accrediting authority~~. This may be desirable, for example, when a laboratory first applies for accreditation or when a laboratory fails a study and wishes to quickly re-establish its history of successful performance. These additional studies are not distinguished from the routinely scheduled studies; that is, they shall be reported and are counted and scored the same way and ~~must~~shall be at least 30 calendar days apart.

2.7.4 Failed Studies and Corrective Action

Whenever a laboratory fails a study, it shall determine the cause for the failure and take any necessary corrective action. It shall then document in its own records and provide to the ~~p~~Primary ~~a~~Accrediting ~~a~~Authority both the investigation and the action taken. If a laboratory fails two out of the three most recent studies for a given PT field of testing, its performance is considered unacceptable under the NELAC PT standard for that field. The laboratory ~~must~~shall then meet the requirements of initial accreditation as described in Section 2.7.2 - Initial and Continuing Accreditation.

2.7.5 Second Failed Study

The PT Provider reports laboratory PT performance results to the ~~p~~Primary ~~a~~Accrediting ~~a~~Authority at the same time that it reports the results to the laboratory. If a laboratory fails a second study out of the most recent three, as described ~~above~~in Section 2.7.4, the ~~a~~Primary Accrediting ~~a~~Authority shall take action, pursuant to ~~c~~Chapter 4, within 60 calendar days to determine the accreditation status of all methods for the unacceptable analyte(s) for that program and matrix.

There may be occasions in which the PT Provider has shipped one or more samples for NELAP accreditation which do not meet the quality control requirements of Appendix B, and the provider has not in a timely manner notified all affected laboratories or Accrediting Authorities as described in Section A.10 of this standard. In this case, an AA, upon review of summary data or other relevant documentation, may choose not to use the results of the analyte(s)/matrices to support the accreditation status of the laboratories. In order to justify not using the results, the AA shall first contact the PT Provider and attempt to resolve the situation. If after notifying the PT Provider, the AA still chooses to pursue a complaint against the provider, the AA shall submit a written complaint to the Accrediting Authority Review Board (AARB). The AARB will evaluate the complaint. If the complaint is determined to be valid, then the AA shall submit the written complaint to the PTOB/PTPA which initially accredited the provider for the particular analyte(s) and matrices. The AA shall follow all procedures for filing complaints as specified by the PTOB/PTPA. The AA may determine that the affected laboratories shall either wait until the next regularly scheduled PT testing

round to analyze another PT for the analyte(s)/matrices, or may require the labs to obtain and analyze a supplemental sample, and repeat the test.

2.7.6 Scheduling of PT Studies

A Primary ~~a~~Accrediting ~~authorities~~Authority may specify ~~the~~which months that laboratories within its authority are required to participate in ~~NELAP PT programs.~~ NELAC PT programs. If the Primary Accrediting Authority chooses to specify the months, then it shall adhere to the required semiannual schedule. If the Primary Accrediting Authority does not specify the months, then the laboratory shall determine the semiannual schedule.

2.7.7 Withdrawal from PT Studies

A laboratory may withdraw from a PT study for an analyte(s) or for the entire study if the laboratory notifies both the PT Provider and the Primary Accrediting Authority before the closing date of the PT study. This does not exempt the laboratory from participating in the semiannual schedule.

~~*APPENDIX A*~~

~~CHAPTER 2,~~

PROFICIENCY TESTING
APPENDIX A

PT PROVIDER APPROVAL CRITERIA

A.~~0.~~0 SCOPE

This ~~A~~appendix describes the responsibilities and requirements a ~~P~~proficiency ~~T~~testing (PT) ~~P~~provider shall meet in order to be a Proficiency Testing Oversight Body (PTOB) /Proficiency Test Provider Accreditor (PTPA) Approved PT Provider. In order for a PT Provider to participate in the NELAC PT ~~P~~program, a ~~P~~provider ~~must~~shall be approved by a PTOB/PTPA. The criteria provided below are designated to ensure the integrity and technical excellence of the NELAC PT ~~P~~program while allowing all qualified ~~P~~providers to participate in the program.

A.1.~~0~~ APPROVAL PROCESS

The process for approval of a PT Provider includes a biennial on-site inspection by a PTOB/PTPA to ensure that the technical criteria of this appendix are being met. At the discretion of the PTOB/PTPA, the PT Provider may be requested to confirm their ability to perform analyses within the required limits through participation in a proficiency testing program operated by the PTOB/PTPA, or through the analysis of unknown samples provided by the PTOB/PTPA. Providers are also required to submit the results of PT programs operated for NELAC to the PTOB/PTPA for review and evaluation. The PT Provider agrees to accept the findings and decisions of the PTOB/PTPA as final.

A.2.~~0~~ QUALITY SYSTEM REQUIREMENTS

The manufacturing quality system used by the PT Provider ~~must~~shall meet the requirements of both International Organization for Standardization (ISO) 9001 for the design, production, testing, and distribution of performance evaluation samples and the requirements of ISO Guide 34, Quality System Guidelines for the Production of Reference Materials. The design and operation of the PT Provider's proficiency testing program ~~must~~shall meet the requirements of ISO Guide 43, Proficiency Testing by Interlaboratory Comparisons. The testing facilities used to support the verification, homogeneity, and stability testing required in Appendix B of this document ~~must~~shall meet the requirements of both ISO Guide 25, General Requirements for the Competency of Testing and Calibration Laboratories and Chapter 5, Quality Systems, of the NELAC standards. The ability to meet the ISO 9001 quality system requirement may be fulfilled through registration of the PT Provider's quality system to American National Standards Institute (ANSI) standards by a Registrar Accreditation Board (RAB) accredited registrar. However, a biennial on-site inspection by the PTOB/PTPA demonstrating continuing conformance is required.

A.3.~~0~~ PROVIDER FACILITIES AND PERSONNEL

Each ~~P~~provider is required to have systems in place to produce, test, distribute, and provide data analysis and reporting functions for any series of samples for which they are requesting approval. Similarly, the ~~P~~provider shall have in place sufficient technical staff, instrumentation, and computer capabilities as may be required by the PTOB/PTPA to support the production, distribution, analysis, data collection, data analysis, and reporting functions of the samples. No portion of the production, testing, distribution, data collection, data analysis, nor data reporting functions may be outside the control of the PT Provider for any particular study, since it is essential that the confidentiality of the samples be maintained throughout the PT study. For the purposes of this requirement "control" can mean ownership or that the subcontracted service is performed under an agreement which specifically ensures the ability of the ~~P~~provider to access and restrict the distribution of information related to these services. Any subcontracted services ~~must~~shall be assessed by a PTOB/PTPA and meet the same criteria as the PT Provider.

A.4~~.0~~ SAMPLE FORMULATION REVIEW

The PT Provider ~~must~~shall demonstrate to the PTOB/PTPA, by the submission of appropriate data, that the sample formulation for which the PT Provider is seeking approval shall permit participating laboratories to generate results that fall within the sample acceptance ranges established by the NELAC Standing Committee on Proficiency Testing and meet the criteria of the ~~National~~"National Standards for Water Proficiency Testing Studies, Criteria Document" (USEPA).

A.4.1 Release of Information

In support of the ~~above~~ requirement in Section A.4.0, PTOBs/PTPAs ~~agree to~~shall treat all sample formulation information submitted to them for review as the proprietary information of the PT Provider submitting the information. Such formulation information shall not be released by a PTOB/PTPA without the prior written consent of the PT Provider.

A.5~~.0~~ PROVIDER CONFLICT-OF-INTEREST REQUIREMENTS

PT Providers seeking approval shall document to the satisfaction of the ~~PTOB~~PTOB/PTPA that they do not have a ~~conflict-of-interest~~conflict of interest with any laboratory seeking, or having, NELAP accreditation. PT Providers shall notify the ~~PTOB~~PTOB/PTPA of any actual or potential organizational conflicts of interest, including but not limited to:

a) Any financial interest in a laboratory seeking, or having, NELAP accreditation;

b) The sharing of personnel, facilities or instrumentation with a laboratory seeking, or having, NELAP accreditation.

The PT Provider is also required to inform all internal and contract personnel who perform work on NELAP PT samples of their obligation to report personal and organizational conflicts of interest to the PTOB/PTPA. The ~~P~~provider shall have a continuing obligation to identify and report any actual or potential conflicts of interest arising during the performance of work in support of NELAC PT programs. If an actual or potential organizational conflict of interest is identified during performance of work in support of NELAC PT programs, the PT Provider shall immediately make a full disclosure to the PTOB/PTPA. The disclosure shall include a description of any action which the ~~P~~provider has taken or proposes to take, after consultation with the PTOB/PTPA, to avoid, mitigate or neutralize the actual or potential conflict of interest. The PTOB/PTPA may reevaluate a PT Provider's Approval status as a result of unresolved conflict of interest situations. Any conflict of interest disputes between the PT Provider and the PTOB/PTPA may be appealed to NELAP for a final determination.

A.5.1 Ban on Distribution of Samples

PT Providers shall not sell, distribute, or provide samples used in the NELAC PT program prior to the conclusion of the study for which they were designed. Providers ~~further agree~~shall not ~~to~~ sell, distribute, or provide samples of identical formulation and concentration to those samples which it is currently using in a NELAC study.

A.6~~.0~~ CONFIDENTIALITY OF PT STUDY DATA

The PT Provider shall demonstrate to the PTOB/PTPA that is has systems in place to ensure that the confidentiality of data associated with NELAC PT samples and programs are not compromised. PT Providers shall not release the Prepared Value of any sample currently being used in a NELAC

PT study prior to the conclusion of the study. ~~The PT Provider also agrees that the acceptance ranges provided to them by either NELAC, or the PTOB/PTPA, are the proprietary information of NELAC, or the PTOB/PTPA, and shall not be disclosed by the PT Provider without the written approval of the PTOB/PTPA.~~

A.7~~.0~~ DATA REVIEW AND EVALUATION

The NELAP designated PTOB/PTPA shall review the data from every PT Provider's studies to ensure that acceptance limits used to evaluate laboratories are consistent with national standards as established by NELAC. The PTOB/PTPA shall also evaluate the performance of the PT Providers by monitoring, and reporting, to both the ~~P~~providers and the NELAC Standing Committee on Proficiency Testing the pass/fail rates of all ~~P~~providers on all samples tested. A PTOB/PTPA is required to investigate any PT Provider whose pass/fail rate is statistically different from the national average.

A.8~~.0~~ COMPLAINTS & CORRECTIVE ACTION

Written complaints received by the PT Provider regarding technical or procedural aspects of the studies they conduct ~~must~~shall be submitted to the PTOB/PTPA. The PT Provider shall resolve the complaint to the satisfaction of the PTOB/PTPA. The PTOB/PTPA is the sole judge of the adequacy of the corrective action taken by the PT Provider. The PTOB/PTPA shall provide NELAP with an annual summary of all PT Provider complaints received during the prior year.

A.9~~.0~~ LOSS OF PROVIDER APPROVAL

PT Providers who fail to meet the requirements of these standards may be subject to loss of their approval as a NELAC PT Provider. Providers may lose approval to provide individual sample sets based upon review of PT study data by a PTOB/PTPA as required in Appendix A, Section A.7. Similarly, PT Providers who fail to meet the requirements of Appendix A, Sections ~~A2~~A.2 through ~~A6~~A.6, on a continuous basis may lose their approval as a ~~PTPA-approved~~PTOB/PTPA-approved PT Provider for all samples.

A.9.1 Periodic Review of PT Providers

A PTOB/PTPA may at any time, review the performance of any approved PT Provider against these standards. Based upon this review, the PTOB/PTPA may decide that the approval status of a PT Provider be revoked, adjusted, limited, or otherwise changed based upon failure to meet one or more of the specified requirements.

A.9.2 Revocation of Approval

Should a PTOB/PTPA propose to revoke or suspend a provider's approval for failure to meet the requirements of these standards, the PTOB/PTPA shall inform the provider of the reasons for the proposed revocation or suspension and the procedures for appeal of such a decision. The due process rights of the provider shall be protected during any revocation or suspension proceedings. The final decision on the revocation or suspension of a provider's approval to supply PT samples for the NELA~~C~~P accreditation ~~program~~ resides with the Executive Director of NELAP. If the provider loses NVLAP accreditation it shall lose NELAP approval to supply samples for the NELAC PT program.

A.10 Notification of Sample Integrity

The provider is responsible for notifying all laboratories and Primary Accrediting Authorities when a particular analyte was determined to not meet the requirements of Appendix B or is deemed of unacceptable quality for NELAC purposes, within 30 calendar days of the study closing date.

~~*APPENDIX B*~~

PROFICIENCY TESTING
APPENDIX B

PT SAMPLE DESIGN
& ACCEPTANCE GUIDELINES

B.~~0.~~0 INTRODUCTION

An integral element of the NELAC PT ~~P~~program ~~S~~standards is the assurance of PT samples which are of high quality, well documented, homogeneous, and stable. In order to meet the goals of NELAC, the PT samples used in the program ~~must~~shall also provide all laboratories with samples which offer a consistent challenge. All PT samples ~~must~~shall meet all applicable specifications of these standards~~.~~

~~**B.1.0**~~.

B.1 SAMPLE FORMULATION APPROVAL

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The PT Provider shall demonstrate the adequacy of sample formulation to the satisfaction of the ~~PTPA~~PTOB/PTPA. The criteria for formulation adequacy are that the sample shall provide equivalent challenge to the laboratories under test as similar samples for the same parameters as other providers, and that the sample shall exhibit laboratory acceptance rates, measured as provider percentage pass/fail performance, consistent with other samples used in the program for the same parameters.
End Of Moved Text

B.1.1 Adequacy of the Sample Formulation

The testing and verification protocol required to establish sample equivalency shall be agreed to by both the PT Provider and the PTOB/PTPA on a case by case basis. It is the responsibility of the PT Provider to demonstrate the adequacy of sample formulation to the satisfaction of the PTOB/PTPA.

B.1.2 PT Sample Composition

PT Providers may choose to leave one or more specific analyte(s) out of PT samples, yet may still include those analyte(s) in the PT study to be counted and scored with the present analytes. The guidelines in this section apply only to PT samples that contain analytes listed in the following NIST program designations: water supply (WS) regulated volatiles, WS unregulated volatiles, WS pesticides, WS herbicides, water pollution (WP) haloaromatics/halocarbons, and WP pesticides. Analytes from different program designations may not be combined. The value assigned to these unspiked analytes would be zero. A PT Provider may choose not to include analytes; however, a minimum number of analytes shall be present in every PT sample. The PT Provider shall prepare samples according to the following criteria:

a) PT samples that are to be scored for one to ten analytes must include all of these analytes.

b) PT samples that are to be scored for ten to 20 analytes must include at least ten of these analytes or 80% of the total, whichever number is greater.

c) PT samples that are to be scored for more than 20 analytes must include at least 16 of these analytes, or 60% of the total analytes, whichever number is greater.

d) If following (b) or (c) above and a percentage of the total number of analytes in the sample in a fraction, the fraction shall be rounded up to the next whole number. For example: 16 analytes × 0.80 = 12.8 = 13 analytes in sample.

e) PT Providers shall use a random selection process to determine which parameters will be assigned zero values within any given PT sample.

All other PT samples must contain all the analytes of interest within the concentration ranges as required by this standard.

B.2 VERIFICATION OF PREPARED VALUE

All PT samples used ~~in the~~for obtaining or maintaining NELA~~C program must~~P accreditation shall be analyzed by the PT ~~p~~Provider prior to shipment to the laboratories to ensure suitability for use in the program. The Prepared Value of the sample shall be used to establish acceptance criteria, and it ~~must~~shall be verified by analysis. PT ~~p~~Providers ~~must~~shall verify the Prepared Value by direct analysis against National Institute of Standards and Technology (NIST) Standard Reference Materials (SRM), if a suitable NIST SRM is available for use. If a NIST SRM is not available then verification ~~must~~shall be performed against an independently prepared calibration material. An independently prepared calibrant is one prepared from a separate raw material source, or one prepared and documented by a source external to the provider.

B.~~1~~2.1 Relative Standard Deviation of Verification Analysis

The method used by the PT ~~p~~Provider for verification analysis ~~must~~shall have a relative standard deviation of not more than 50% of the relative standard deviation predicted at the Prepared Value by the laboratory acceptance criteria being used by NELAC for each parameter. The relative standard deviation of the provider's verification method shall be established by a method validation study, and the suitability for use shall be approved by the NELAP designated Proficiency Testing Oversight Body (PTOB)/Proficiency Test Provider Accreditor (PTPA).

B.~~1~~2.2 Quality Control Check of the Prepared Value

The prepared value for every parameter in all PT samples ~~must~~shall be verified by analysis. The prepared value of the analyte is verified if the mean of the verification analyses is within 1.5 standard deviations, as calculated as described in Sections C.1.1.1 or C.1.1.2, of either a) the prepared value if an unbiased verification method is used or b) the mean value for the analyte as calculated in Sections C.1.1.1 or C.1.1.2 if a biased method is used. The standard deviation of the verification analyses also ~~must~~shall be less than one standard deviation as calculated in Sections C.1.1.1 or C.1.1.2. For analytes that are evaluated using fixed percentages as defined in Section C.1.1.1, standard deviations are calculated by assuming that the fixed percentage is equal to two standard deviations.

B.~~2.0~~3 HOMOGENEITY TESTING

PT sample homogeneity is essential to ensuring that all laboratories are treated fairly. Therefore, the purpose of the homogeneity testing procedure is to establish at the 95% confidence level that all samples distributed to the laboratories have the same Prepared Value for every parameter to be evaluated. Homogeneity testing is required on all PT samples prior to sample shipment to the laboratories.

B.~~2~~3.1 Homogeneity Testing Procedure

The homogeneity of the samples ~~must~~shall be established using a generally accepted statistical procedure. The procedure selected by the PT ~~p~~Provider ~~must~~shall be capable of evaluating the relative consistency of each analyte across the production run, and ~~must~~shall be performed on the final packaged samples. The procedure ~~must~~shall establish at the 95% confidence level that the

Prepared Value is consistent across the production run. Samples, or parameters, which fail to pass the homogeneity testing criteria cannot be used in the NELAC PT program to evaluate laboratories.

B.~~2~~3.2 Suitable Homogeneity Testing Procedures

A suitable homogeneity testing procedure shall be capable of comparing the between sample to within sample standard deviation across the PT ~~p~~Provider's packaging run, and shall ensure comparability with 95% confidence. Suitable homogeneity testing procedures are available in both ISO Guide 35 for the Certification of Reference Materials and in the ISO Reference Material Committee (REMCO)-Association of Official Analytical Chemists (AOAC) Harmonized Protocol for the Proficiency Testing of Analytical Laboratories. However, the homogeneity testing procedure used by the PT ~~p~~Provider ~~must~~shall be approved for use by the PTOB/PTPA.

B.~~3.0~~4 STABILITY TESTING

The samples used in the NELAC PT program ~~must~~ shall be verified as stable for the period of each study.~~-~~ Therefore, the stability of all samples, and parameters, ~~must~~shall be established by the PT ~~p~~Provider following the close of data submission from the laboratories. The samples are considered stable for the period of the study if the Mean analytical value as determined after the study for each parameter falls within the 95% Confidence Interval calculated for the prior to shipment verification testing used to establish the Prepared Value. The testing procedure used for stability testing ~~must~~shall be approved for use by the PTOB/PTPA.

~~**B.4.0 SAMPLE FORMULATION APPROVAL**~~

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~~**B.4.1 Adequacy of the Sample Formulation**~~

~~The testing and verification protocol required to establish sample equivalency shall be agreed to by both the PT provider and the PTOB/PTPA on a case by case basis. It is the responsibility of the PT provider to demonstrate the adequacy of sample formulation to the satisfaction of the PTOB/PTPA.~~

B.~~5.0~~ DATA REPORTING BY PT PROVIDERS

The results of sample Prepared Value verification, homogeneity, and stability testing ~~must~~shall be available to the participating laboratories. All data developed by the provider in support of verification testing, homogeneity testing, and stability analysis ~~must~~shall be provided to any laboratory participating in the program upon request after the close of the study. Providers shall supply PT data to the Primary Accrediting Authorities, as per Section 2.6, in a format acceptable to the Primary Accrediting Authority.

B.5.1 Verification and Homogeneity Reports

The data developed by the PT ~~p~~Provider in support of verification~~,~~ and homogeneity~~, and stability~~ testing shall be supplied in summary format to the PTOB/PTPA in an electronic format to be determined by the PTOB/PTPA. Verification and homogeneity data ~~must~~shall be supplied to the PTOB/PTPA prior to sample distribution to the laboratories.

B.5.2 Laboratory Data and Stability Reports

All summary data from the laboratories and the results of stability testing ~~must~~shall be provided to the PTOB/PTPA in an electronic format to be determined by the ~~PTOB~~PTOB/PTPA within 30 calendar days of the close of the study.

PROFICIENCY TESTING
APPENDIX C

~~CHAPTER 2, PROFICIENCY TESTING~~

PT ACCEPTANCE CRITERIA
AND
PT PASS/FAIL CRITERIA

C.~~0~~.0 PURPOSE, SCOPE, AND APPLICABILITY

This ~~A~~appendix defines the criteria to be used by any entity which seeks to participate as a NELAP-approved Proficiency Test Provider ~~in the NELAC Program~~ for scoring the results obtained from the analyses of samples in any NELAC PT ~~S~~study. ~~Two distinct sets of scoring criteria are defined: 1) whether or not an individual analyte result is either "Acceptable" or "Not Acceptable" and 2) whether or not a laboratory's initial PT performance for a group of interdependent analytes can be evaluated as "Pass" or "Fail".~~ The PT Providers shall submit all laboratories' performance rating(s) to the Primary Accrediting Authority, as described in Chapter 2 of the NELAC standards, to be used as a tool for determining a laboratory's accreditation status. PT acceptance limits and pass/fail criteria are established on a ~~P~~program-matrix-analyte basis~~-~~.

C.1~~.0~~ ANALYTE ACCEPTANCE LIMITS

Acceptance limits are established for each analyte~~. Whether or not a laboratory has passed or failed a group of interdependent analytes is based on the number of results that are determined to be acceptable.~~ as described in this appendix.

C.1.1 Analyte Acceptance Limit Categories

Acceptance limits are separated into two categories. Results for analytes with acceptance limits determined as described in Sections C.1.1.1 and C.1.1.2 shall be used in the determination of a laboratory's PT ~~P~~program-matrix-analyte ~~-~~ pass/fail evaluation. Results for analytes with acceptance limits determined as described in Section C.1.1.3 shall not be used as part of the ~~P~~program-matrix-analyte ~~pass/fail~~acceptable/not acceptable evaluation.

C.1.1.1 Analytes with USEPA Established Acceptance Limits

PT Providers shall utilize the proficiency test acceptance limits that have been established by USEPA in the ~~National~~"National Standards for ~~w~~Water ~~p~~Proficiency ~~t~~Testing ~~studies~~, Criteria Document" where they apply. The ~~National~~"National Standards ~~are~~for Water Proficiency Testing, Criteria Document" is incorporated into this ~~A~~appendix by reference. EPA's established proficiency test acceptance limits for chemical analytes are typically expressed in the following manner:

- **Prepared ± fixed percentage.** Acceptance limits shall be set at plus and minus the published fixed percentage of the analyte's verified prepared value.

- **Mean ± 2 standard deviations.** For those analytes for which the NELAC Standing Committee on Proficiency Testing has established linear regression equations relating prepared value to mean and prepared value to standard deviation, acceptance limits shall be set using said equations and the sample's verified prepared value. Linear regression equations may only be used for prepared values that fall within the range of prepared values used to establish said equations. In the event that there are no linear regression equations available for a given analyte, that analyte shall be treated as described in Section C.1.1.3.

C.1.1.2 Analytes with ~~a~~Acceptance ~~l~~Limits ~~derived from regression equations e~~Established by the NELAC Standing Committee on Proficiency Testing

~~When USEPA Program regulations for establishing acceptance criteria are not available~~For analytes not included in the "National Standards for Water Proficiency Testing, Criteria Document," Proficiency Test providers shall ~~set~~use acceptance limits ~~using regression equations that predict~~

~~the mean and standard deviation for an analyte in a given range of concentrations. Regression equations shall be derived~~established by the NELAC Standing Committee on Proficiency Testing and shall be made available to ~~PTPA-approved~~PTOB/PTPA-approved PT Providers by the PT Committee Chair or the Executive Director of NELAP. Data from sources such as the USEPA PE studies, interlaboratory results from professional organizations such as ASTM, other ~~p~~Proficiency ~~testing p~~Test Providers, commercial and non-profit organizations, shall be used to establish the ~~equations~~evaluation criteria. All ~~regression equations~~evaluation criteria shall be approved by the NELAC Standing Committee on Proficiency Testing prior to use by a ~~PTPA-approved~~PTOB/PTPA-approved PT Provider. ~~For these analytes, the PT Provider shall use the sample's verified prepared value and said equations to determine the mean and standard deviation.~~

C.1.1.3 Experimental Data: Analytes without ~~p~~Promulgated ~~a~~Acceptance ~~l~~Limits or ~~e~~Established ~~r~~Regression ~~e~~Equations

For those analytes not included in categories C.1.1.1 or C.1.1.2, e.g., newly regulated analytes, or analytes in a matrix that have not been fully evaluated in interlaboratory studies, NELAC acceptance limits shall be established only after interlaboratory data has been collected for a minimum of one year unless the NELAC Standing Committee on Proficiency Testing determines that sufficient data have been collected in less time. The data obtained during the one-year period shall be referred to as "experimental data". The NELAC Standing Committee on Proficiency Testing shall derive regression equations to be used to establish acceptance limits for analytes in the experimental category after sufficient data have been collected. The laboratory shall receive a copy of its own experimental data from the PT Provider at the conclusion of the PT study.

C.2.~~0~~ ACCEPTABLE PT RESULTS FOR CHEMICAL ANALYTES IN POTABLE WATER AND NON-POTABLE WATER PT SAMPLES

A laboratory's PT analyte result is acceptable when it falls within the regulatory promulgated acceptance limits (Section C.1.1.1). For Section C.1.1.2 analytes, PT Providers shall use the PT sample's verified prepared value and said regression equations to determine the mean and standard deviation. Acceptance limits shall be set at the mean ± two standard deviations for potable water analytes and the mean ± three standard deviations for non-potable water analytes. A result is acceptable when it falls within these derived acceptance limits.

C.3.~~0~~ NOT ACCEPTABLE PT RESULTS FOR POTABLE WATER AND NON-POTABLE WATER PT SAMPLES

A laboratory's result for any analyte is considered unacceptable if it meets any of the following criteria:

a) The result falls outside the ~~USEPA's promulgated~~ acceptance limits ~~(Section C.1.1.1) or outside prediction interval derived from established regression equations (Section C.2.0)~~;

b) The ~~lab~~laboratory reports a result for an analyte not present in the PT sample (i.e., a false positive);

c) The ~~lab reports a result of "Not Detected", (or similar indication of no detection), for an analyte present in the PT sample (i.e., a false negative);~~

~~NOTE: If a laboratory reports a result less then the lowest concentration contained in the NELAC-approved PT concentration range for an analyte present in the PT sample~~

~~at a concentration within the NELAC-approved PT concentration range, the result shall be classified as a false negative and scored as "not acceptable".~~

~~d)~~ ~~The lab~~laboratory does not withdraw from a study as described in Section 2.7.7, and fails to submit its results to the PT Provider on or before the deadline for the PT study.

C.4.~~0~~ ADDITIONAL REQUIREMENTS FOR PT PROVIDERS

PT Providers shall examine all data sets for bimodal distribution and/or situations where results from a given method have disproportionally large failure rates or reporting anomalies to the Proficiency Testing Oversight Body/Proficiency Test Provider Accreditor. All proficiency test data are to be submitted to the PTOB/PTPA in the format specified by the PTOB/PTPA and shall be reviewed annually by the NELAC Standing Committee for Proficiency Testing for the purpose of revising existing and establishing new ~~linear regression equations.~~evaluation criteria.

~~C.5.0 NELAC PT STUDY PASS/FAIL CRITERIA~~

~~NELAC PT samples are designed to meet the requirements of Chapter 2 and associated appendices. Once data acceptability has been determined as described in Sections C.1 through C.3 of this appendix, the laboratory's PT "Pass" or "Fail" evaluation is determined as described in this Section. Pass/Fail criteria are used when groups of interdependent analytes are evaluated as a unit for the laboratory's initial demonstration of proficiency.~~

~~C.5.1 Interdependent Analyte PT Samples~~

~~Interdependent analyte PT Samples are those that are analyzed using methods in which the ability to correctly identify and quantitate a series of analytes is indicative of the laboratory's ability to correctly determine the presence or absence of similar analytes. Examples of interdependent PT Samples are those used for the following series of analytes; volatiles, semivolatiles, pesticides, herbicides, etc..~~

~~C.5.2 Non-interdependent Analyte PT Samples~~

~~Non-interdependent PT Samples are those that are analyzed using methods in which the ability to correctly identify and quantitate an analyte or a series of analytes in a sample is not indicative of the laboratory's ability to correctly identify and quantitate similar analytes. Non-interdependent analyte PT samples may contain a single analyte, e.g., pH, BOD, TSS, etc., or may contain multiple analytes, e.g., metals, major ions, etc.~~

~~C.5.3 Promulgated USEPA Pass/fail Criteria~~

~~In all cases, promulgated USEPA pass/fail criteria, e.g., drinking water volatiles as listed in 40 CFR 141.61(a), subsection (m)(1), shall be used as NELAC PT pass/fail criteria as applicable. The criteria described in Section 5.4 shall be used in the absence of promulgated USEPA pass/fail guidelines.~~

~~C.5.4 Pass/fail Criteria For Interdependent Analyte PT Samples~~

C.4.1 Additional Matrix/Analyte Groups

Additional matrices and/or analytes may be added to the NELAC PT fields of testing at the request of any AA, EPA program office, or PTOB / PTPA-approved PT Provider. The request for the

addition of an analyte must include at a minimum ten sets of interlaboratory data on the analyte in the particular matrix. Each data set must contain a minimum of twenty valid data points. The NELAC Standing Committee on Proficiency Testing ~~pass/fail evaluations for Interdependent Analyte PT samples shall be determined as follows. To receive a score of "Pass", a laboratory must produce "Acceptable" results as defined in Section C.1 for 80% of the analytes in an Interdependent Analyte PT Sample. Greater than 20% "Not Acceptable" results shall result in the laboratory receiving a score of "Fail" for that series of analytes. For example, a laboratory must report all "Acceptable" results for an Interdependent Analyte PT Sample containing 1-4 analytes, may report no more then one "Not Acceptable" result for a Sample containing 5-9 analytes, two "Not Acceptable" results for a Sample containing 10-14 analytes. A "Not Acceptable" result for the same analyte in two consecutive PT studies shall also result in the laboratory receiving a score of "Fail" for that analyte.~~ shall review the data and develop an initial set of laboratory acceptance limits based upon the needs of the AAs, EPA, and the laboratories. Laboratory acceptance limits developed by the PT Committee on any new matrix/analyte combinations shall be reviewed annually by the PT Committee. The purpose of this annual review is to ensure that the limits represent the actual capabilities of the laboratories.

~~*APPENDIX D*~~

~~CHAPTER 2,~~

PROFICIENCY TESTING
APPENDIX D

PROFICIENCY TESTING OVERSIGHT BODY/ PROFICIENCY TEST PROVIDER ACCREDITOR

D.~~0~~.0 PURPOSE, SCOPE, AND APPLICABILITY

This ~~A~~appendix defines the qualifications, scope of responsibilities and requirements for a NELAP designated Proficiency Testing Oversight Body (PTOB)/Proficiency Test Provider Accreditor (PTPA) as defined in Section 2.2.2 of the NELAC document. In addition to complying with the requirements of this ~~A~~appendix, a PTOB/PTPA, for this oversight function, shall comply with the applicable requirements described in Chapter 2 and associated Appendices A (PT Provider Acceptance Criteria), B (PT Sample Design and Acceptance Guidelines), and C (Criteria for Setting PT Data Acceptance Limits).

D.1.~~0~~ TECHNICAL AND ADMINISTRATIVE QUALIFICATIONS

An organization shall demonstrate to the NELAC Standing Committee on Proficiency Testing by the submission of a current Statement of Qualifications that it has the technical expertise, administrative capacity, and financial resources sufficient to implement and operate a national program of PT Provider evaluation and oversight. In the event that the organization is not a nationally or internationally recognized authority, the NELAC Standing Committee on Proficiency Testing reserves the right to request further documentation detailing the organization's qualifications. The organization shall meet the following general requirements:

a) Demonstrate the capability to manage and evaluate complex environmental reference materials in a variety of matrices;

b) Demonstrate expertise in statistical applications as related to large interlaboratory performance evaluation programs;

c) Demonstrate the capability to conduct on-site audits of PT Providers;

d) Demonstrate the capability to conduct technical reviews of Initial Applications;

e) Demonstrate a knowledge and understanding of the ISO guides 9001, 34, 43, and Chapter 2 of the NELAC standards including Appendices A, B, and C.

D.2.~~0~~ PTOB/PTPA RESPONSIBILITIES REGARDING INITIAL ASSESSMENT OF PT PROVIDERS

PTOB/PTPA responsibilities are described in this section. The primary responsibility of a PTOB/PTPA is the oversight and ongoing monitoring and evaluation of the PT Providers. The oversight activities of a PTOB/PTPA shall be designed to ensure that the PT Provider meets the requirements specified in Chapter 2 and Appendices A, B and C. Any variations from these requirements shall be approved by the NELAC Standing Committee on Proficiency Testing prior to a body being approved as a NELAC PTOB/PTPA. All activities described herein shall be conducted by a PTOB/PTPA.

D.2.1 Development of Standard Operating Procedures and Forms

PTOBs/PTPAs shall develop the Standard Operating Procedures (SOPs) necessary to conduct the PT Provider evaluation process. These documents shall be based upon the requirements of Chapter 2 of the NELAC standards and the associated Appendices A, B, and C. The NELAC Standing Committee on Proficiency Testing has the authority to review and approve, as necessary, the SOPs developed by a PTOB/PTPA.

D.2.1.1 SOP(s) for the Assessment Process

The PTOB/PTPA shall develop and implement SOP(s) including but not limited to: the initial application submittal and review process, on site inspection, submittal of final reports to NELAP, the procedures for determining that a PT Provider's approval be revoked, the procedures for appealing approval determinations, and any other procedures deemed necessary by NELAC.

D.2.1.2 Initial Application

A PTOB/PTPA shall develop the initial application process to be submitted by PT Providers applying for approval as PT Providers of NELAC samples. The application shall include questions regarding the qualifications of the organization seeking approval. In addition to completing the initial application process, a PTOB/PTPA shall require that the PT Provider submit copies of its current ISO 9001 registration certificate or any other documents which detail the quality systems required by the provisions of Chapter 2 and associated Appendices.

D.2.1.3 SOP(s) for On-Site Inspections and Checklist(s)

A PTOB/PTPA shall develop SOP(s) for conducting consistent, effective, on-site inspections of PT Providers. The SOP shall include policies which describe the circumstances for conducting any additional inspections, and circumstances for determining whether on-site inspections shall be announced or unannounced. A PTOB/PTPA shall develop standard, consistent checklist(s) to be used during any and all inspections of PT Providers.

D.2.2 Initial Application Review and On-site Inspections

A PTOB/PTPA shall follow the procedures described in this section for the review of applications and on-site inspections of any candidate PT Provider.

a) A PTOB/PTPA shall review the initial application documents, described in D.2.1.2, for compliance with the PT Provider qualifications described in Appendix A and other applicable documents.

b) A PTOB/PTPA shall review the sample designs used by the PT Provider for compliance with Appendix B and other applicable documents.

c) A PTOB/PTPA shall review the PT analyte and sample scoring procedures used by the PT Provider for compliance with Appendix C and other applicable documents.

d) Following the review of the Initial Application and associated documents, a PTOB/PTPA shall conduct an on-site inspection of the PT Provider. The PT Provider shall be provided with checklist(s) to be used during the inspection as part of the initial application process.

e) Following the inspection, a PTOB/PTPA shall conduct an exit meeting with the PT Provider, which shall include discussion of deficiencies and discrepancies found; however, a PTOB/PTPA may further revise the findings after the closing of the exit meeting, if necessary.

The inspection shall include, at a minimum:

1) Review of the quality system for adherence to the requirements of Appendices A, B and C;

2) Review of staff qualifications and technical expertise necessary to produce acceptable proficiency testing samples;

3) Review of the sample manufacturing and verification procedures to ensure that the requirements of Appendices A and B are met;

4) Review of the procedures in place to ensure that all personnel are aware of and abide by standards of conduct for PT Providers and confidentiality of sample values; and

5) Review of data reporting systems to ensure that the requirements of Appendix C are met within the time periods specified in Chapter 2. —

f) A PTOB/PTPA shall send a draft report to the PT Provider after the completion date of the inspection. A PTOB/PTPA shall allow the PT Provider to review and comment on the draft if the PT Provider finds any discrepancies and determines that revisions are necessary. A PTOB/PTPA shall then submit a final inspection report to the PT Provider after the completion of the on-site inspection. The final report may only contain discrepancies and findings identified during the on site inspection or discussed during the exit briefing.

g) A PTOB/PTPA shall allow the ~~P~~provider to submit their response to the report. In order for the ~~P~~provider's response to be considered acceptable, a PTOB/PTPA shall require that it include a description of corrective actions necessary to meet the criteria of Chapter 2, and Appendices A, B, and C.

D.3.~~0~~ PTOB/PTPA RESPONSIBILITIES REGARDING APPROVAL OF PT PROVIDERS

A PTOB/PTPA shall utilize the appropriate final report and associated documents submitted by the PT Provider to grant or deny approval to that ~~P~~provider.

D.4.~~0~~ PTOB/PTPA RESPONSIBILITIES FOR ONGOING OVERSIGHT OF PT PROVIDERS

A PTOB/PTPA shall conduct ongoing oversight of all approved PT Providers. The oversight shall include at a minimum:

a) the use of referee laboratories to verify the concentrations of analytes in randomly selected PT Provider samples;

b) the statistical monitoring of PT Provider's study data to detect occurrences which indicate samples of unacceptable quality, i.e., failure rates that exceed expected norms, analyte standard deviations that exceed expected intervals, and analyte mean recoveries which are significantly above or below historical trends. The ongoing monitoring criteria to be used by a PTOB/PTPA shall be developed by NELAC.

c) biennial on-site inspections of the PT ~~p~~Provider review and monitoring of critical operational parameters of the PT ~~p~~Provider, i.e., change in senior management, sale of the company.

d) on-site inspections of the PT ~~p~~Provider for cause.

Based upon the results of its ongoing oversight, the PTOB/PTPA may determine that the ~~P~~provider's approval status be reevaluated.

D.5.~~0~~ DEVELOPMENT AND MAINTENANCE OF A COMPREHENSIVE PT DATABASE

A comprehensive PT database shall be developed and maintained by the PTOB(s)/PTPA(s) in conjunction with NELAC.

D.6.~~0~~ COMPLAINTS AND CORRECTIVE ACTION

A PTOB/PTPA shall evaluate all complaints that it receives regarding either approved or candidate PT Providers. ~~–~~If the PTOB/PTPA determines that a complaint warrants investigation, the PTOB/PTPA shall notify the ~~P~~provider of the complaint.~~-~~ The PT Provider is required to resolve the complaint to the satisfaction of the ~~PTOB/PTPAA~~PTOB/PTPA. A PTOB/PTPA shall provide to the NELAC Standing Committee on Proficiency Testing a summary of all PT Provider complaints received the previous year.

D.7.~~0~~ LIST OF APPROVED PT PROVIDERS

A PTOB/PTPA shall maintain a list of approved PT Providers. ~~-~~The list shall be maintained on a continuing basis on an electronic bulletin board or similar means and shall be readily available to laboratories seeking NELA~~C~~P accreditation, state ~~a~~Accrediting ~~a~~Authorities and other interested parties. ~~–~~PT Providers ~~must~~shall agree to abide by the provisions of NELAC regarding the advertising and marketing use of the designation, "NELAP-designated PTOB/PTPA Approved Proficiency Test Provider".

D.8.~~0~~ SPONSORSHIP OF ANNUAL *NELAC PROFICIENCY TESTING CAUCUS*

The PTOB(s)/PTPA(s) shall, in conjunction with NELAC, sponsor an annual *NELAC Proficiency Testing Caucus*. ~~-~~The *Caucus* shall, if possible, be held in conjunction with the annual NELAC meeting.~~-~~ The purpose of the *Caucus* is to provide a forum for PT Providers, Accrediting Authorities, laboratories, federal agencies, and other interested parties to exchange information regarding the PT study results of the previous year. ~~-~~The *Caucus* shall include technical presentations and open discussions on means to improve the ~~P~~proficiency ~~T~~testing aspect of NELAC with a continuing goal of improving the quality of environmental data generated by the NELAC accredited laboratories.

D.9.~~0~~ PTOB/PTPA ETHICS

This section describes the overall ethics and standards of conduct that ~~must~~shall be adhered to in order for a PTOB/PTPA to implement and administer a successful PT Provider oversight program. A PTOB/PTPA shall serve as an impartial body designed to objectively evaluate information about PT Providers and use this information to make sound determinations regarding ~~P~~providers' approval status. ~~–~~A~~–~~ PTOB/PTPA shall be able to certify to any interested party that it is free of any organizational or financial conflict of interest, which would prevent it from complying with the requirements of Appendix D.~~–~~ A PTOB/PTPA shall remain unbiased in evaluating information gathered and received including inspection reports, referee sample results, complaints, and any other information obtained regarding a PT Provider. ~~-~~The PTOB/PTPA shall evaluate all information gathered and received about a ~~P~~provider related to providing NELAC PT samples, and determine which information is relevant to the approval status of a ~~P~~provider, and provide that information to NELAP, the ~~p~~Primary Accrediting Authorities, the laboratories, and the public as appropriate.

D.10.~~0~~ CONFIDENTIALITY

A portion of the information provided to a PTOB/PTPA by the PT Provider in the course of its inspection and oversight activities shall be proprietary in nature. A PTOB/PTPA shall agree to maintain the confidentiality of proprietary information provided to it by the PT ~~p~~Provider.

~~*APPENDIX E*~~

~~CHAPTER 2, PROFICIENCY TESTING~~

PROFICIENCY TESTING
APPENDIX E

MICROBIOLOGY

E.~~0.~~0 PURPOSE

This appendix outlines the requirements for microbiological proficiency testing under the Safe Drinking Water (SDWA) and Clean Water (CWA) Acts. ~~-~~Microbiological testing for other USEPA ~~P~~programs shall be added as required.~~-~~ Semi-annual proficiency testing is required per the schedule contained in Section 2.4.

E.1~~.0~~ SAMPLES

E.1.1 SDWA Samples

PT Providers shall present samples as either as full volume samples or preparations easily reconstituted to full volume samples. ~~-~~For the SDWA, there shall be ten 100+ ml. samples (as presented or after reconstitution) for the qualitative determination (Presence/Absence) of total coliform and fecal coliform (or *E. coli*).~~-~~ Sample sets which are provided to the laboratories shall contain bacteria that produce the following:

- Verification as total and fecal coliforms (E. coli).
- Verification as total coliforms, but not as fecal coliforms.
- Bacterial contaminates which shall not verify as total or fecal coliforms.

Furthermore, each set shall contain the following samples:

- One to four samples containing an aerogenic strain of Escherichia coli for total and fecal coliform positive results using all USEPA approved methods.
- One to four samples containing Enterobacter sp. or other microorganisms ensuring a total coliform positive and fecal coliform negative result using all USEPA approved methods.
- One to four samples containing Pseudomonas sp. or other microorganisms ensuring a total and fecal coliform negative result using all USEPA approved methods.
- One to four blank samples.
- Optionally, one sample for the quantitative determination of Heterotrophic Plate Count.

Sample sets for qualitative analysis shall be randomly composed of samples that are Total coliform absent, Total coliform only present and Fecal coliform (E. coli) present.

E.1.2 CWA Samples

For the CWA, one sample shall be provided for the quantitative determination of Total coliform or Fecal coliform. ~~-~~Providers may require laboratories to analyze samples during a fixed time period after sample shipment or at any time during the testing period which shall not exceed the time limit set in Chapter 2.

E.2~~.0~~ SAMPLE PREPARATION AND QUALITY CONTROL

Proficiency test sample providers shall select bacterial strains and *holding media* that produce the appropriate biochemical reactions for *all* approved analytical methods. ~~-~~This shall be documented by analyses performed by the provider prior to sample shipment. ~~-~~The provider ~~must~~shall also demonstrate that the samples are stable by analysis of a randomly selected set either after the study

closing date or in the case of a study with a fixed testing period, on the last working day of the testing period.

E.3.0 SCORING

E.3.1 Qualitative Analyses, *SDWA Samples*

Participating laboratory results shall be considered Acceptable or Unacceptable when compared to the known presence or absence of Ttotal coliform or Ffecal coliform (or *E. coli*) bacteria. Passing shall be considered as nine out of ten samples having acceptable results, and no false negatives reported.

E.3.2 Quantitative Analyses

Quantitative result data sets shall be evaluated by analytical method using standard statistical analysis with outlier rejection. Most Probable Number data shall be transformed to logs prior to statistical analysis. Acceptable results are those that are within the 99% confidence limits as set by the mean, standard deviation and set size *(n)* for their respective data set.

E.3.2.1 Requirement for Quantitative Data Set Size

Each PT pProvider's microbiological data set shall be comprised of at least 20 valid data points for each method evaluated. Sample sets of less than 20 data points may be used only with the approval of the PTOB/PTPA.

PROFICIENCY TESTING
APPENDIX F

ENVIRONMENTAL TOXICOLOGY

F.0 PURPOSE, SCOPE, AND APPLICABILITY

This appendix defines the criteria applying the proficiency testing (PT) program to the following environmental toxicology programs: 1) whole effluent toxicity (WET), 2) sediment toxicity, and 3) soils toxicity.

F.1 RATIONALE

Accreditation for environmental toxicology testing laboratories will be based on Proficiency Testing and on "onsite" audits, the latter including but not limited to an evaluation of personnel qualifications, facility acceptability, quality system and SOPs, status of data/reports generated and routine standard toxicant testing. Proficiency Testing provides a snapshot of the laboratory's capability, however, due to the number of variables inherent to environmental toxicology testing it cannot carry the same weight as PT samples for chemical analytes. PT samples will be comprised of unknown concentrations of EPA's historical reference toxicant materials. Every effort will be made by the PTOB/PTPA working together with the providers to reduce the number of variables in each method (i.e., organism age, etc.) while following the routine language of the EPA protocols.

F.2 LABORATORY ENROLLMENT IN PROFICIENCY TESTING PROGRAMS

F.2.1 Required Level of Participation

Laboratories seeking accreditation for environmental toxicology shall participate in at least one PT study per year for each method code as designated (method code includes matrix, organism, exposure system, and endpoint).

F.2.2 Requirements for Laboratory Testing of PT Study Samples

a) Analyze within 30 calendar days of sample receipt; report results within 30 calendar days of completion.

b) Samples will be analyzed exactly the way the lab always runs these tests (this includes dilution water, number of replicates, water changes, etc., within the limits of the method code) – "as close to real world testing as possible".

F.3 PT CRITERIA FOR LABORATORY ACCREDITATION

F.3.1 Initial and Continuing Accreditation

Except that for initial or continuing accreditation, completion dates of successive proficiency testing studies for a given field of testing must be at least annual (i.e., not more than 12 months apart) and at least 30 calendar days apart (i.e., participation in a second round or remedial study may not occur within 30 calendar days of the first or failed study). Failure to meet the annual schedule will be regarded as a failed study. Results other than acceptable/unacceptable may apply.

F.4 FIELDS OF TESTING

The environmental toxicology PT program will be organized by fields of testing based on method [including matrix, test organism, and exposure system and endpoint(s)]. Laboratories may choose to participate in one or more PT fields of testing, or portions thereof.

F.4.1 Whole Effluent Toxicity (WET) Method Codes

Test Organism	Test Conditions	Method Code[1]
Pimephales promelas	48-h acute, non-renewal, synthetic MHW[2]	11
Pimephales promelas	7-d chronic, daily renewal, synthetic MHW	15
Ceriodaphnia dubia	48-h acute, non-renewal, synthetic MHW	17
Ceriodaphnia dubia	7-d chronic, daily renewal, synthetic MHW	21
Daphnia pulex	48-h acute, non-renewal, synthetic MHW	32
Mysidopsis bahia	48-h acute, non-renewal, synthetic SW[3]	42
Mysidopsis bahia	7-d chronic, daily renewal, synthetic SW	43
Menidia beryllina	48-h acute, non-renewal, synthetic SW	44
Menidia beryllina	7-d chronic, daily renewal, synthetic SW	45
Cyprinodon variegatus	48-h acute, non-renewal, synthetic SW	46
Cyprinodon variegatus	7-d chronic, daily renewal, synthetic SW	47

[1] Method Code refers to EPA DMR-QA method summaries
[2] MHW = moderately hard freshwater (EPA formula)
[3] SW = synthetic sea water (Hawaiian MarineMix or Forty Fathoms)

F.4.1.1

Prior to NIST accreditation of PT providers for Environmental Toxicology methods, laboratories seeking WET accreditation will be assessed through on-site audit and evaluation of EPA DMR-QA test results. During this interim period, a failed DMR-QA endpoint will require: 1) a formal response to the AA with an explanation of probable cause for the endpoint failure and description of corrective actions to be taken (where appropriate) and 2) a decision by the AA to accept the response or require additional on-site audits. There will be no loss of accreditation based solely on PT results during this interim period.

Upon accreditation of Environmental Toxicology PT providers and programs, a WET PT endpoint failure will require successful completion of remedial studies (conducted at least 30 calendar days apart) until two acceptable results are obtained. Decisions for the need of additional on-site audits will continue to rest with the AA. Loss of accreditation will not be based solely on the results of PT studies.

As the Environmental Toxicology PT program develops and PT data are analyzed and complied into a database, the requirements of the PT program may become more rigid. The default for the WET PT program is accreditation without PT samples.

F.4.2 Sediment Toxicity (Solid Phase)

Test Organism	Test Conditions	Method Code
Freshwater amphipod	10-d, static, renewal, synthetic MHW	TBS[1]
Midge larvae	10-d, static, renewal, synthetic MHW	TBS
Saltwater amphipod	10-d, static, non-renewal, synthetic SW @ 20 ‰	TBS
Polychaete worm	10-d, static, non-renewal, synthetic SW @ 28 ‰	TBS
[1] TBS = To Be Specified		

F.4.2.1

Accreditation for whole sediment toxicity methods will be based solely on the on-site audit until further notice.

F.4.3 Soil Toxicity

Test Organism	Test Conditions	Method Code
Eisenia foetida survival test	14-d static, non-renewal, 24L:0D	TBS[1]
Lettuce (Lactuca sativa) seed germination test	120-h static, non-renewal, 16L:8D	TBS
Lettuce (Lactuca sativa) root elongation test	120-h static, non-renewal, 0L:24D	TBS
[1] TBS = to be specified		

F.4.3.1

Accreditation for soil toxicity methods will be based solely on the on-site audit until further notice.